UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/100,088	06/19/1998	PETER G. BROWN	1606.0020004	8182

26111 7590 08/25/2003

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
JONES, HUGH M	

ART UNIT	PAPER NUMBER
2123	21

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PRC

Office Action Summary

Application No.	Applicant(s)
09/100,088	Brown
Examiner	**Art Unit**
Hugh Jones	2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 2, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 4-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. Applicant has requested that Examiner review six co-pending applications including all art contained therein. As Applicant can appreciate, this places an extreme burden on the Examiner *(as well as the other six Examiners)* because the seven Examiners must review each application *every time art is added* to *each* application, and *each time* the claims in each application are *amended.* In the interest of compact prosecution, the Examiner would be appreciative if the Applicant would kindly supply copies of the indicated applications. The Examiner will consider any additional prior art provided in a proper IDS form 1449.

2. Applicants have been silent in response, but are reminded that they have requested that the Examiner sign and initial the IDS statements.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. What does *optimal design* mean (last limitation of claim 1, for example)?

6. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: "... *contains information that* ***can be used to determine*** *an optimal design for a biopharmaceutical batch process manufacturing facility*". There is no limitation disclosing *how it can be used* or *actually using* it. Applicant is claiming a *simulation* of process scheduling for a specific industry.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over [Skeirik (*of record*) *or* Atherton (Applicant's IDS) *or* Iwasaki et al. (Applicant's IDS) *or* Litt et al. (Applicant's IDS) *or* Furukawa et al. (*of record*) *or* Carrette et al. (*of record*) *or* Leitch et al. *or* Ketcham et al. *or* Bernstein et al. *or* Ehrlich et al. *or* Arai et al. *or* Britt et al. (*Applicant's supplemental IDS*)] and further in view of the taking of [*Official Notice*] and [*Applicant's Own Admission*].

9. Skeirik discloses: a process control system with reconfigurable expert rules and control modules. From the abstract;

> "An integrated system for process control in which a process supervisor procedure (which is preferably the top-level procedure) is configured as a modular software structure, with modules that can be revised by a user at any time, without significantly interrupting the operation of the process supervisor. The modular software can define control parameters for many process control procedures, and can retrieve data from many sources (preferably including a historical database of process data, which can provide time-stamped data). The supervisor can also call on various expert subprocedures. Preferably the expert subprocedures can also be modified by an authorized user at any time, by calling up and editing a set of natural-language rule templates which correspond to the rules being executed by the expert subprocedure."

See also: fig. 1-2, 7-8, 15-18; col. 1-18 (details concerning the expert system and its use in process control).

10. Atherton discloses: real world modeling and process control. Col. 1 discloses the background; col. 2 discloses details concerning "due dates" and scheduling theory; col. 3 discloses simulation models of factories and their use in schedule generation; col. 4 discloses details concerning batch, sampling, and process control; col. 4 discloses the taking into account of equipment reliability and other details involved in process modeling; col. 10 discloses an algorithm for process modeling; cols. 11-16 disclose details concerning sequences, batching, scheduling rules.

11. Iwasaki et al. discloses: "Production system with order of processing determination". See: col. 2-3 (details concerning scheduling a processing line); col. 6 (use of sampling data).

12. Litt et al. disclose: "Expert system and method for batch production scheduling and planning." See: abstract; fig. 2-7; col. 1-2 (details concerning the use of rule-based expert systems in process scheduling, batch scheduling, delivery dates, production constraints).

13. Furukawa et al. disclose a production control system. See: abstract; fig. 3a (scheduling and its interaction with the production line), fig. 3c (lead time), fig. 4a (scheduling), fig. 4c (overview), fig. 5 (scheduling), fig. 20-23 (details about scheduling), fig. 31 (table), fig. 41 (tables, pointers, scheduling), fig. 60-63 (overview); see text corresponding to said figures.

14. Carrette et al. disclose: Method and apparatus for real-time control. See: abstract; fig. 1-2, 4-8, 13, 21-24 and corresponding text.

15. Leitch et al. disclose, "*A real-time knowledge based system for product quality control.*" The abstract discloses:

> "An ICI plant in the north of England has two batch reactors producing a large number of products consisting of ethoxylates. It is controlled by a Foxborough Fox 1/A process sequence control computer. The task of the plant operators is to set the 'recipe' on the Fox 1/A to make products at the desired quality and to initiate and monitor the process sequence. When a batch has been produced they judge its quality and can take a sample for laboratory analysis. If they judge it necessary they may make an adjustment or take other remedial action. The paper concerns an expert system which makes recommendations to the operator when he makes his decisions. *To achieve this it must monitor and form judgements on the plant and raw materials affecting product quality; provide a prediction of product quality; estimate errors in instrumentation; and provide a justification for its recommendations.*

Index Terms:

> general-purpose detergents; chemical reactors; real-time knowledge based system; product quality control; ICI plant; batch reactors; ethoxylates; Foxborough Fox 1/A process sequence control computer; expert system; batch processing (industrial); chemical industry; chemical variables control; expert systems; process computer control; quality control."

See, also: sections entitled "Application", "The knowledge based system", and particularly, "The quality control system".

16. Ketcham et al. disclose a generic simulator for continuous flow manufacturing. They disclose quality control (abstract, col. 1, page 609); tooling layout (col. 2, page 610), product batching (col. 1, page 611), and a process simulation (section 5).

17. Bernstein et al. diclose a simulation-based decision support system for a speciality chemicals production plant that can be used in an off-line mode. Col. 1, page 1263 discloses that the simulation is carried out prior to any capital investment, and also discusses the database, used in the simulation. Section 2 discloses scheduling and operations issues. Section 3 discloses a simulation execution module including simulation of batch processing and sequencing and a knowledge base.

18. Ehrlich et al. disclose AIM which is a manufacturing process modeller. Section 1.1 discloses that the simulation is carried out before physical implementation. Section 1.3.1 discloses the model. Section 1.3.2 discloses modelling of scheuling. Section 3 discloses the GUI interface and simulation of batch processing.

19. Arai et al. disclose an automatic analysis system. See the abstract. Col. 2, line 51 to col. 2, line 63 disclose:

> *"That is to say, according to the first aspect of the present invention, there is provided an automatic analysis system which comprises an analytical equipment and a host computer connected to the analytical equipment, said host computer comprising control means for giving identification numbers for identification to pieces of analysis information such as an analytical measurement test sample name, an analytical measurement test item name, an analytical measurement test method*

name, an analytical measurement tester name, an analytical measurement test requester, i.e., a customer name as well as lower limit values, errors, analysis accuracies and units of an analytical measurement test, respectively, further giving identification numbers to the pieces of analysis information, respectively, to relate the pieces of analysis information to each other, grouping a predetermined number of the pieces of analysis information to form pieces of group information, giving identification numbers to the pieces of group information, respectively, further grouping a predetermined number of the pieces of group information to form pieces of group information, and then giving identification numbers to the pieces of group information, respectively, and storage means for storing the pieces of analysis information and group information to which the identification numbers are given by the control means.

According to the second aspect of the present invention, there is provided an automatic analysis system which comprises an analytical equipment and a host computer connected to the analytical equipment, said host computer comprising control means having functions of giving first identification numbers to pieces of analysis information, respectively, to mutually identify the pieces of analysis information and to relate the pieces of analysis information to each other, grouping a predetermined number of the pieces of analysis information to form pieces of first group information, giving second identification numbers to the pieces of first group information, respectively, further grouping the pieces of first group information in accordance with a predetermined viewpoint to form pieces of second group information, and then giving third identification numbers to the pieces of second group information, respectively, and storage means for storing the pieces of analysis information to which the first, second and third identification numbers are given by the control means.

Moreover, *in the present invention, the respective pieces of analysis information are grouped in accordance with a common attribute to form the first group information, and the respective pieces of analysis information are grouped in accordance with the property or purpose of the respective pieces of analysis information such as a chemical composition, an analytical measurement test method or an analytical result report preparation method to form the second group information. Furthermore, the identification numbers are given to the pieces of the first and second group information, and these pieces of the information are then stored, whereby the handling of the information can be preferably improved.*

In the present invention, the respective pieces of analysis information basically comprise measured data and relevant information other than the measured data, and to these pieces of analysis information, identification numbers are given. Then, they are stored in storage means. These pieces of analysis information are retrieved by the control means, read in a mutually related manner, processed and then edited, and the final results are output by output means such as a printer.

Furthermore, *in present invention, the respective pieces of analysis information necessary for an analytical measurement test such as a test item, a test sequence, a test method and test conditions are read from the storage means prior to the execution of the analytical measurement test, and these pieces of analysis information are output as an arrangement document, whereby artificial errors can be prevented and the analytical measurement test can be correctly and smoothly carried out*.

Moreover, in the middle stage of the analytical measurement test, the analysis progress state is read out from the storage means, whereby reference can be made and the control of the analytical measurement test can be accurately and quickly accomplished. In addition, the efficiency of the analytical measurement test can be improved."

20. Britt et al. disclose (abstract):

"A software system simulates and optimizes a processing plant design. The software system includes a plurality of equipment models for simulating each piece of equipment in the processing plant design. A sequential modular simulation routine executes the equipment models in a first mode to define a first set of values of the operating parameters of the processing plant design. An optimization routine executes the equipment models in a second mode. The optimization routine utilizes the first set of values for the operating parameters from the sequential simulation routine and subsequently determines values of the operating parameters at which the processing plant design is optimized. The equipment models after execution by the sequential simulation routine and optimization routine store the first and second sets of values for the operating parameters in a common plant model file. Hence, the plant model file holds values computed during the sequential simulation routine as well as those computed during the optimization routine."

Col. 4, line 36 to col. 5, line 26 disclose:

"Applicants have discovered that the better software system for simulating and optimizing process plant designs is one which:

a) solves the initial plant model through sequential modular simulation. This generates an initial point. and

b) generates an equation oriented plant model which is initialized from the solution in a). This equation oriented model is then used for data reconciliation, parameter estimation, optimization, and simulation.

Such a system provides an improvement over the prior art.

By way of summary, there are two basic parts to the present invention. The first basic part of the present invention enables the same equipment model to be used in both (i) a simulation by a sequential modular computation, and (ii) the simultaneous simulation (or optimization) of the entire plant model. In other words, each equipment model can be executed in two modes as follows.

Mode A:

Given equipment operating parameters and the feed conditions, the equipment (process unit) model solves for the product streams of the corresponding piece of equipment. This means that the equipment model can be executed as a part of the sequential modular computation of the plant model.

Mode B:

An equipment model is able to participate in the simultaneous simulation of the entire plant model by computing items which are needed by the simulator which solves the total plant model.

To that end, each equipment model of the present invention has a dual execution mode capability, as described in detail below.

The second basic part of the present invention is that each equipment model, at the end of the plant simulation or optimization, stores the results to a plant model file, which is used with both modes of the equipment model execution.

This part of the present invention enables the solution of the sequential modular simulation and the solution of the simultaneous simulator/optimizer to be mutually shared. Hence, initial plant simulation is carried out by a sequential modular simulation. The results are stored in the plant model file. The results of the sequential modular simulation are then used as the initial, starting point for the simultaneous simulation and optimization of the plant model.

Results obtained by the simultaneous simulation of the plant model are also stored in the plant model file. Therefore, one can use these results to run a sequential modular plant simulation.

In the present invention, initial simulation of a desired process plant by a sequential modular routine enables the convergence of the plant model (i.e., solution thereof) with a very small number of specifications or initial guesses entered by the plant model developer/engineer. This solution then serves as the starting point for the optimization of the plant model by the simultaneous simulation routine. Since the simultaneous simulation routine starts from a feasible point (solution by the sequential modular routine), the simultaneous simulator/optimizer converges to an optimum point in a robust manner."

See, also: fig. 1-2; col. 1, line 45 to col. 4, line 33.

21. [Skeirik (*of record*) *or* Atherton (Applicant's IDS) *or* Iwasaki et al. (Applicant's IDS) *or* Litt et al. (Applicant's IDS) *or* Furukawa et al. (*of record*) *or* Carrette et al. (*of record*) *or* Leitch et al. *or* Ketcham et al. *or* Bernstein et al. *or* Ehrlich et al. *or* Arai et al. *or* Britt et al.] do not disclose biopharmaceutical applications and details pertinent to biopharmaceutical applications. Applicant has admitted that (page 23, lines 13-27, specification) that the invention is a general simulation procedure for batch processes *other* than *just* for biopharmaceutical applications. Official Notice is taken that one of ordinary skill in the art at the time of the invention would

recognize and choose the appropriate process and quality control variables as necessary for the particular application.

***Response to Arguments* (paper # 20)**

22. Applicant's arguments filed 6/19/2003 have been fully considered but they are not persuasive.

***Response to Arguments - 101 Rejections* (pp. 2-3; paper # 20)**

23. Applicant's arguments are persuasive and the 101 rejections are withdrawn.

***Response to Arguments - 112(2) Rejections* (pp. 3-4; paper # 20)**

24. Applicants arguments are not persuasive. Applicants argues that the limitation is in the form of a "whereby" clause (thus providing an "intended use" and from which Applicants conclude that there are "no missing steps") and alleges that "The term as used in the claim, however, is not vague or indefinite". However, these arguments do not address the merits of the rejection. Allegations about skilled artisans are merely attorney argument in the absence of evidence.

***Response to Arguments - 103 Rejections* (pp. 4-10; paper # 20)**

25. Applicant's arguments are not persuasive because Applicants have merely argued against the references piecemeal. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are

based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

26. Applicants piecemeal argument is followed by the statement (in response to the taking of Official Notice), "Applicant feels these asserts are both broad and vague". Applicant's *opinions* are noted, however, this does not constitute a *challenge* to the taking of Official Notice or attempt at reasoning. Applicants also state, "*For similar reasons, Applicants also respectfully disagrees with the Examiner's prior Official Notice.*" The Examiner respectfully submits that this is not a *seasonable* challenge, let alone a challenge, as per MPEP 2144.03.

27. The Examiner would like to point out that various portions of the specification appear to take the same position as that taken in the Official Notice which Applicants now complain are *broad* and *vague*. Applicant has admitted that (page 23, lines 13-27, specification) that the invention is a general simulation procedure for batch processes *other* than *just* for biopharmaceutical applications and that the invention rests in the ***application*** of the scheduling/simulation to biopharmaceutical batch processing. Official Notice was taken that one of ordinary skill in the art at the time of the invention would recognize and choose the appropriate process and quality control variables as necessary for the particular application. Compare this to the specification which states (lines 13-27) the following:

> "Fig. 6 further illustrates exemplary process parameters table 504. *The operational parameters in the process parameters are those parameters necessary to simulate a particular unit operation*. The unit operation identification codes of process parameter table 504 are used in the

> cross-reference step 506 to assign the parameters from the process parameters table 504 to the unit operation list 502. ***Examples*** *of operational parameters are the solutions involved in a particular unit operation, temperature, pressure, duration agitation, scaling, volume,* ***etc***. Additionally, the process parameters table defines all of the individual tasks and task duration involved in each unit operation. ***It should be noted however, one of ordinary skill in the art could expand the process parameters table to encompass additional unit operations and production processes for other batch process industries suc as chemical pharmaceutical, specialty chenical, food, bevearge and cosmetics. Such expansion would allow the present invention to simulate and schedule additional batch production processes for other such batch processes."***

(Emphasis added).

28. **It is noted that Applicants have not addressed all the components in the 103 rejection.** Applicants are reminded that the 103 was based, in part, on Applicant's Own Admission. **Applicants are *silent* with respect to Applicant's Own Admission.**

Conclusion

29. This is a RCE of applicant's earlier Application No. 09/100,088. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be:

directed to:

Dr. Hugh Jones telephone number (703) 305-0023, Monday-Thursday 0830 to 0700 ET, ***or*** the examiner's supervisor, Kevin Teska, telephone number (703) 305-9704. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, telephone number (703) 305-3900.

mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to:

(703) 308-9051 (for formal communications intended for entry)
or (703) 308-1396 (for informal or draft communications, please label "*PROPOSED*" or "*DRAFT*").

Dr. Hugh Jones

Primary Patent Examiner

August 24, 2003

HUGH JONES Ph.D.
PRIMARY PATENT EXAMINER
TECHNOLOGY CENTER 2100